REMARKS

Claims 1-23 are pending in the above-identified patent application. By this Amendment, claims 1, 2, 14, 16, 18 and 23 are amended. No new matter is added. Reconsideration of the application is respectfully requested in view of the above amendments and the remarks set forth below.

Double Patenting Rejection

The Office Action rejects claims 1-23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent No. 5, 900,376 in view of BIO-RAD Catalog of 1993, Life Science Research Products, pages 71-74.

As the Office Action notes, "[a] timely filed terminal disclaimer...may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application." This application is commonly owned with U.S. Patent No.5,900,376. Applicants have timely filed herewith a terminal disclaimer. Thus, it is respectfully submitted that the claims 1-23 under the judicially created doctrine of obviousness-type double patenting is overcome. Reconsideration and withdrawal thereof are respectfully requested.

Section 112, Second Paragraph, Rejection

The Office Action also rejects claims 1-23 under 35 U.S.C. 112, second paragraph, as being indefinite for containing asserted informalities.

In the above amendments, Applicant has deleted the terminology "a natural product" without prejudice and replaced the terminology objected to with the terms "a polysaccharide, a polyphenol, a tannin, an alkaloid, a pigment" (see page 4, lines 5-11 in the present spefication) and the terms "a reducing agent, a protein denaturant, an amine, Hepes, a tris-buffer" (see example-6 in the present specification).

Regarding the terminology "a common laboratory agent," those of ordinary skill in the art understand that this terminology refers to those chemical agents when present in protein solution do not either render the protein in the solution insoluble or destroy the protein.

In the above amendments, Applicant has replaced the term "SDS" with the full terminology --sodium dodecyl sulfate-- as is understood by those of ordinary skill in the art and as defined on page 2, lines 16 and 28 of the present specification.

In the above amendments, Applicant has changed the dependency of claim 14 to claim 13 where the centrifugation in the step (b) being repeated is defined.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims aims 1-23 under 35 U.S.C. 112, second paragraph, are respectfully requested.

Section 103 Rejection

The Office Action rejects claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Bensadoun et al. (Analytical Biochemistry, Volume 70, pp. 241-250, 1976) taken with Carraro et al. (Biochem. & Biophys. Res. Commun., Vol. 200, No. 2, pp. 916-924, 1994). This rejection is traversed.

The Office Action asserts that Bensadoun et al. "disclose like the instantly claimed invention a method of protein precipitation in dilute solution by mixing the protein solution with an acidic agent and/or component such as Trichloracetic acid (TCA) and then adding or introducing into the mixture of the protein precipitate-forming agent such as sodium deoxycholate and a salt such as sodium chloride...".

However, the Office Action mischaracterizes Bensadoun et al. in at least the following three ways:

1. Bensadoun et al. teach **first** mixing protein solution with sodium dexycholate and **then** adding or mixing trichloric acid not, as asserted in the Office Action, **first** acid and then sodium deoxycholate. Applicant respectfully submits that one of skill in the art would certainly expect that the order of mixing of various agents would affect the outcome of the method. Therefore, one of ordinary skill in the art would not expect that choosing any order of mixing of the two critical agents would achieve the same results.

Furthermore, in the presence of SDS in protein solution, Bensadoun et al.would not work. The Examiner is respectfully requested to read the specification of the present specification on pages 1-3, particularly page 2, lines 22-30.

2. The Office Action asserts that Bensadoun et al. teach use of "a salt such as sodium chloride..." This assertion misrepresents the teachings of the prior art. In particular, Bensadoun et al. describe the use of sodium chloride for the correction of the reaction blank and not for the "method of protein precipitation in dilute protein solution" as claimed by the examiner. It is noted that Bensadoun et al. page 248, last paragraph recites "[t]his blank contribution was eliminated by adjusting the molarity of the sample to 1M NaCl before protein precipitation."

3. As far as the listed agents in Table 1 are concerned, none of the agents were used by Bensadoun et al. for protein precipitation as asserted in the Office Action.

Regarding Carraro et al., it is important to first focus on the totality of the scope of the invention. The preamble of present claim 1 reads as follows:

"A method of preparation of protein sample solution for analysis, wherein the **protein sample solution** contains one or more of non-protein agents selected from a group consisting of an anionic detergents, a cationic detergent, a non-ionic detergent, a zwitterionic detergent, a sulfobutane, a lipid, a natural product, a salt, and a common laboratory agent, wherein after the preparation of the protein sample the protein in the sample is **quantitatively recovered** and is **substantially free from the non-protein** agents **originally present in the sample**..."

The critical components of the scope of the invention are; first, "**protein sample solution**", which represents universality of the method and includes any and all protein, irrespective of its physical or chemical characteristic (including hydrophobic as well as hydrophilic proteins). Second, **quantitative recovery** of the proteins, third, recovery of "**substantially free** (proteins) **from the non-protein agents originally present in the sample.**

Carraro et al. teach away from the scope of the instant invention.

The Office Action asserts that Carraro et al teach "a two step precipitation method that removes free SDS detergents from dilute solution of protein, thus allowing for the recovery and quantification of the protein themselves". This is not a correct reading of Carraro et. al. The correct reading of the prior art is as follows.

Carraro et al teach a two step precipitation method that removes free SDS detergents AS WELL AS 25-50% OF THE HYDROPHOBIC, LOW IONIC INSOLUBLE PROTEINS FROM THE SOLUTION (See Carraro Abstract, Results, and page 922) from dilute solution of protein, thus allowing for the recovery and quantification of RESIDUAL ABOUT 50-80% of the TOTAL protein IN THE ORIGINAL SOLUTION.

The Office Action further asserts that Carraro et al teach, as follows:

"the protein containing supernatant is then treated with a trichloric acid solution and potassium chloride, which serves to precipitate the proteins."

The Office Action again incorrectly cites the teaching in the prior art. The correct reading of Carraro et teaching is as follows:

"the protein containing supernatant is then treated with a trichloric acid solution and potassium chloride, which serves to precipitate the RESIDUAL SDS-proteins COMPLEXES" (See Carraro et al. page 917, last two paragraphs) .

Carraro et al further state "to optimize the selective precipitation of free KDS, temperature, solutes, and pH of solutions must be carefully controlled during the procedure. Changes in these parameters allow to separate peculiar proteins from complex mixtures".

Carrraro et al, describe a method for removal of free SDS from protein solutions. The Carraro et al method can not be used as a universal method for protein precipitation (it specifically excluded hydrophobic proteins and low ionic insoluble proteins from the method). The method requires careful control of temperature, solutes, and pH of solutions. Therefore, Carrraro method can not be used as a quantitative method (the method reports a large variation and loses ranging 50-80%, see page 922).

Carraro et al specifically teach that the protein precipitated is not free from SDS (See Carraro Page 917, last two paragraphs). In fact, the protein precipitated is SDS-protein complex, thus containing SDS. It is generally know that SDS-protein complexes may contain 2-3 fold SDS in excess of proteins.

Thus, for at least the above reasons, the applied references, alone or in combination, do not teach or suggest the presently claimed method. In particular, the cited prior art fails to reach the scope of the presently claimed invention, more specifically, quantitative recovery, SDS-free proteins, and applicability to all proteins without requiring any specific control of temperature, solutes, and pH of solutions.

The presently claimed invention, by contrast, is universal and does not have any limitation with respect to the nature of protein nor requiring any specific control of temperature, solutes, and pH of solutions. The presently claimed invention is quantitative (See Example 16) and produces protein substantially free from detergents (Example 12).

With respect to the use of organic solvents, it should be noted that the presently claimed invention does not claim the use of organic solvent for precipitation of protein. In fact, organic solvent is used in the invention after protein precipitation (step b) to encompass the totality of the scope of the invention.

Both applied references, Bensadoun et. al. Carraro et al. teach away from the presently claimed invention. Hence, these two methods would not have been combined, would not work if combined, and in any case are missing elements of the presently claimed invention.

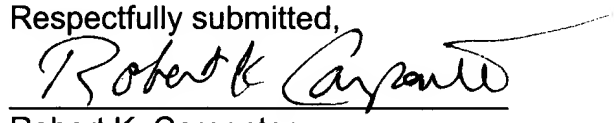
For at least the above reasons, the presently claimed invention would not have been obvious over the combination of Bensadoun et al. taken with Carraro et al. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-23 under 35 U.S.C. 103(a).

Conclusion

In view of the above amendments and remarks, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited. Should the Examiner believe anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

In the event this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. The Commissioner is authorized to charge payment for any additional fees which may be required with respect to this paper to Counsel's Deposit Account 01-2300, referring to client-matter number 108904-00002. Thus, please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, making reference to Attorney Docket No. 108904-00002.

Respectfully submitted,



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